**ISPOR**

**International Society for Pharmacoeconomics and Outcomes Research**

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June 30, 1998

Rec'd 7/10/98 gf

Ms Minnie Baylor-Henry
Drug Marketing, Advertising and Communications Division
Food and Drug Administration
5600 Fishers Lane, HFD - 40, Room 17B04
Rockville, MD 20857

Re: Guidance for Industry - Promotional Use of Health Care Economic Information Under Section 114 of the Food and Drug Administration Modernization Act

Dear Ms Baylor-Henry:

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is a non-profit organization dedicated to uniting the science of pharmacoeconomics and the practice of this science in cost-effective health care decisions. Our organization is organized to act as a scientific leader relevant to research in pharmacoeconomics, health outcomes assessment, and related issues of public policy. The Society represents health care researchers and practitioners including pharmacists, physicians, economists, and other health care professionals involved in pharmacoeconomic analysis and health outcomes assessment.

This letter is to inform the Drug Marketing, Advertising, and Communications Division of the Office of Drug Evaluation I, CDER of the FDA of the Society's intent to comment on the Draft "Guidance for Industry - Promotional Use of Health Care Economic Information under Section 114 of the Food and Drug Modernization Act" submitted to the FDA by the Pharmaceutical Research Manufacturers Association on June 22, 1998.

ISPOR has been actively involved in the development of pharmacoeconomic methodology guidances over the past six months. ISPOR's involvement began January 5, 1998 in Washington with a day-long public briefing on Section 114. The FDA was represented on our program by Ms. Laurie Burke. Other speakers during this Briefing included ISPOR members responsible for drafting this guidance, as well as practitioners who will be affected by this legislation and other government agencies responsible for regulating product promotions.

ISPOR organized another conference in February that addressed a number of important pharmacoeconomics and outcomes research methodological, ethical, and communication issues. This three-day conference (supported, in part, by a grant from the Agency for Health Care Policy and Research), held in Washington, DC, provided an opportunity for the invited health care researchers, practitioners, and government representative to develop consensus on these pharmacoeconomics and outcomes issues. These discussions are the basis for the enclosed Draft Guidance. The Food and



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Administration was represented at this conference by Ms Laurie Burke and Dr. Robert Temple, each of whom participated on discussion panels that developed the seven focused problem statements and recommendation regarding pharmacoeconomics and outcomes research. Over 250 individuals participated in this ISPOR activity. The problem statements and the recommendations will be published in the new journal of the society, *VALUE IN HEALTH-The Journal of the International Society for Pharmacoeconomics and Outcomes Research*

In March, ISPOR hosted a joint meeting of ten professional organizations, representing both health care researchers and practitioners, to discuss a proposed Draft Guidance. A list of the participating organizations is enclosed. The Draft Guidance submitted by PhRMA incorporates the recommendations and suggestions of organization representatives attending this Joint Meeting. You have received some of their comments. Other organizations are currently reviewing this Draft Guidance with their members and will be submitting their letters of recommendation or comment under separate cover.

At the ISPOR Third Annual International Meeting held May 26-30th, the Draft Guidance was presented. At this time, the draft guidance is being submitted to the ISPOR membership for comment. **The ISPOR Executive Board will submit a recommendation after the membership comment period ending August 15, 1998.** We recognize the FDA's abbreviated timetable for the development of this guidance and will respond quickly to any questions or requests from Administration.

The ISPOR initiative to develop consensus on methodological, ethical and communication issues of pharmacoeconomics and outcomes research is continuing. The draft methodology papers from the Pharmacoeconomics: Identifying the Issues Conference will be available at our website, www.ispor.org, for review and comment. At the ISPOR Inaugural European Conference, the ISPOR US consensus development advisory panels on the standardization of pharmacoeconomic methodology will be compared and contrasted with the HARMET initiative in Europe. At the Annual Meeting Fourth General Session, the discussions on the seven methodological, ethical, and communication pharmacoeconomics issues will continue. ISPOR will continue to involve its members during your preparation of the proposed Draft Guidance. We will comment on the Guidance when it is published in the *Federal Register*. **We are willing to assist the Administration on further modifications to this Draft Guidance. If the Administration requires an "Expert" panel during the implementation phase of the guidelines or on an ongoing basis for review of promotional materials, ISPOR can provide this assistance.**

ISPOR is committed to continuous improvement in the standards of pharmacoeconomic research. We believe that we can help in defining best practices and that our involvement will enhance the implementation of the resulting guidelines. We are certain that the U.S. public has much to gain from the effective implementation of guidelines which have the solid support of government , academia, clinicians, and industry.

ISPOR takes its professional responsibility seriously and believes that our involvement in determining the "Best Science" and translation into practice will lead to meaningful enactment of this legislation. If done well, the U.S. public should benefit from this action.

Sincerely,

James E. Smeeding RPh., MBA
ISPOR President

# JOINT MEETING
# DEVELOPMENT OF AN FDA GUIDANCE FOR PROMOTIONAL USE OF HEALTH CARE ECONOMIC INFORMATION

March 17, 1998
Marriott Metro Center
Washington, DC

## Attendees

| HEALTH CARE ORGANIZATION REPRESENTED: | REPRESENTATIVE: |
|---|---|
| American Association of Health Plans (AAHP) | Anthony A. Barrueta<br>Counsel, Government Relations<br>Kaiser Foundation Health Plan, Inc. |
| | Mark P. Okamoto PharmD<br>Clinical Pharmaceutical Scientist<br>Pharmacoeconomics and Clinical Research Group |
| Academy of Managed Care Pharmacy (AMCP) | Richard N. Fry RPh<br>Director of Pharmacy Affairs<br>AMCP |
| | John B. Zatti RPh, MS, CAE, FACA<br>The George Washington University Health Plan |
| American Pharmaceutical Association (APhA) | David Schulke<br>Director, Alliance Development and Regulatory Affairs<br>APhA |
| American Society of Health-System Pharmacists (ASHP) | Colleen O'Malley RPh, MS<br>Director, Center for Managed Care<br>ASHP |
| | Sara Beis RPh, MS<br>Medication Use Policy Pharmacist<br>University of Wisconsin, Madison School of Pharmacy |
| International Society for Pharmacoeconomics and Outcomes Research (ISPOR) | Karl Matuszewski MS, PharmD<br>Director, Technology Assessment<br>University HealthSystem Consortium |
| | John Clouse RPh, MS<br>Vice President, Applied HealthCare Informatics United HealthCare Corporation |
| International Society for Technology Assessment in Health Care (ISTAHC) | Bryan Luce PhD<br>Chief Executive Officer<br>MEDTAP International |

# JOINT MEETING
# DEVELOPMENT OF AN FDA GUIDANCE FOR PROMOTIONAL USE OF HEALTH CARE ECONOMIC INFORMATION

## Attendees (continued)

| HEALTH CARE ORGANIZATION REPRESENTED: | REPRESENTATIVE: |
|---|---|
| Pharmaceutical Research Manufacturers Association - Health Outcomes Work Group (PhRMA-HOWG) | Thomas L. Copmann PhD<br>Director, North American Regulatory Affairs<br>Eli Lilly and Company |
| | Jean Paul Gagnon PhD<br>Director, Health Economics Policy<br>Hoechst Marion Roussel |
| | W. Robert Simons<br>Director of health Economics, Medical & Scientific Affairs Division<br>Sanofi Winthrop Pharmaceuticals |
| Pharmaceutical Care Manufacturers Association (PCMA) | Max Norman Richburg Esquire<br>Senior Policy and Professional Affairs Counsel<br>PCMA |
| | Louise R. Van Diepen<br>Vice President, Clinical Services<br>AARP Pharmacy Service |
| Society for Medical Decision Making (SMDM) | David B. Matchar MD, FACP<br>Director and Associate Professor of Medicine<br>Duke Center for Clinical Health Policy Research |
| Congressional Fellow (AAAS) | Earlene E. Lipowski PhD<br>AAAS Congressional Fellow<br>United States Senate Committee on Labor & Human Resources Majority Staff |